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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,754	11/22/2000	Kathryn K. Lappegard	1189	3443

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EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/718,754

Applicant(s)

LAPPEGARD ET AL.

Examiner

Stuart Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 11, 12, 17 and 21 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☒ Claim(s) 4, 5, 8-10, 13-16, 18-20 and 22-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

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Applicant's election with traverse of Group I claims 1-3, 6, 7, 11, 12, 17, and 21 drawn to SEQ ID NO:1, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the inventions are closely related and the disclosure connects Groups 1, 5, and 8. This is not found persuasive because there is undue burden for search and examination. The inventions are distinct as stated in the previous office action.

The requirement is still deemed proper and is therefore made FINAL.

Objection is made to claims 1, 6, 11, and 21 for containing non-elected material. For purposes of compact prosecution, examination of said claims has proceeded. Applicant is advised to amend the claims.

Objection is made to claim 17 for being dependent on a non-elected claim. Applicant is advised to amend the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 11-12, 17, and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The inventors claim a nucleic acid sequence comprising a promoter sequence that purportedly drives transcription in a seed-preferred manner. Applicants also claim sequences that are 65% or more identical to SEQ ID NO: 1 referred to as the maize jasmonate induced

protein-1 (Jip1) promoter. Using the Genome Walker Kit, Applicants isolated a 5' region of the Jip1 gene promoter from the maize line V3-4 A63 which was used as a probe for isolating a clone from the BAC library made from Mo-17 genomic DNA. They eventually amplified a 1.4 kb upstream piece of DNA which they subcloned into a vector containing the GUS gene with the pinII terminator (i.e. making the construct Jip1::GUS::pin II). The expression pattern of the endogenous gene was analyzed using Northern analysis.

The applicants do not identify structural features unique to the maize Jip1 promoter that would define or describe DNAs that differ from SEQ ID NO:1, yet retain the maize Jip1 spatial and temporal expression pattern. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Given the lack of description for the maize Jip1 promoter, it remains unclear what features identify a maize Jip1 promoter, including a maize Jip1 promoter with 65% homology to SEQ ID NO:1 or sequences that will hybridize to SEQ ID NO:1. Since a maize Jip1 promoter has not been described by specific structural features or by specific function, the specification fails to provide an adequate written description to support the generic claims.

Claims 1-3, 11, 12, 17, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the 1247 bp's 5' of an isolated maize

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Jip1 coding region (SEQ ID NO:1) operably linked to a desired gene and transformed into a maize plant, to obtain expression in 15-40 days-after-pollination (DAP) embryos with some weaker expression in the endosperm and pericarp (referred to further as seed-preferred expression) does not reasonably provide enablement for claims broadly drawn to a sequence that hybridizes to SEQ ID NO:1 under highly stringent conditions, or a sequence having at least 65% sequence identity to SEQ ID NO:1 drawn to plant transformation with the exemplified or non-exemplified promoter regions for obtaining expression in 15-40 DAP embryos with some weaker expression in the endosperm and pericarp. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a nucleic acid specifying the 5' region of a maize Jip1 gene of SEQ ID NO:1, sequences that hybridize to SEQ ID NO:1 and sequences having at least 65% sequence identity to SEQ ID NO:1. The instant specification, however, fails to provide guidance for which base of SEQ ID NO:1 can be altered and still maintain proper spatial and temporal seed-preferred expression. The specification also fails to provide guidance for which base can be deleted and which regions of the sequence can tolerate additions, base-substitutions or recombinations and still be a functional promoter.

Non-coding nucleic acid sequences that exhibit base pair deletions, substitutions or rearrangements, cannot be expected to maintain their promoter or enhancer activity. Izawa et al (1993, J. Mol. Biol. 230 :1131-1144) teach the nucleotides flanking the G-box (CACGTC) and C-box (GACGTC) hexameric cores were shown to affect protein binding activity and specificity of bZIP transcription factors (page 1132, bottom of right column; page 1134, bottom of left

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column). Hao, et al (1998, The J. of Biological Chemistry 273 (41): 26857-26861) investigated the binding activities of ethylene-responsive element-binding proteins (EREBP) to their cis-element GCC box (AGCCGCC). Creating base-pair substitutions within the GCC box modulates binding specificity, implying that different positions within the GCC box are important for differential binding by different EREBP's, in particular, substituting T's for the two G's eliminates binding completely (*supra*, pages 26857, abstract and 26860, left column, 2nd paragraph).

Not only are DNA sequences located 5' to the translation start site (ATG) sensitive to base changes, but in some instances, intronic regions have been shown to be necessary for proper gene expression. Busch et al (1999, Science 285:585-587) and Lohmann et al (2001, Cell 105 :793-803) teach *LEAFY* (*LFY*) and *WUSCHEL* (*WUS*), which have been shown to be transcription factors that together activate proper *AGAMOUS* (*AG*) expression, do so by binding to the second intron of the *AG* gene. A two base-pair mutation within the binding site of either *LFY* or *WUS* eliminates binding of either *LFY* or *WUS*, respectively (Busch et al (*supra*) page 587 left column, 2nd paragraph; Lohmann et al (*supra*) page 799, bottom and top of left and right columns) and changes the temporal and spatial *AG* expression pattern.

Given the unpredictability of determining the function of an isolated nucleic acid other than the 1247 bp's 5' of an isolated maize Jip1 coding region (SEQ ID NO:1) on the basis of its nucleotide sequence alone and the unpredictability of replicating an expression pattern of an endogenous promoter that hybridizes to SEQ ID NO:1 or that specify a sequence having at least 65% identity to SEQ ID NO:1, for the reasons stated above; given the lack of working examples using the maize Jip1 promoter; given the absence of guidance with regard to identification of

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other promoter regions from the multitude of sequences that would hybridize to SEQ ID NO:1, given the state of the prior art which does not provide further guidance about Jip1 promoter regions and given the breadth of the claims which encompass a multitude of sequences that have not been exemplified, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, and 21 and all subsequent dependent claims are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is indefinite as the open language of the claim is confusing and implies that there is another piece of DNA with regulating characteristics that is operably linked to "a second nucleotide sequence selected from the group consisting of". Applicants are requested to amend the language of the claim to read on the elected regulatory element operably linked to a specified DNA sequence.

Claims 1-3 use the abbreviation Jip1 which as stated in the specification is an abbreviation for the Jasmonate induced protein-1 gene. This is indefinite as the three letter abbreviation Jip1 is used and refers to JNK-interacting protein 1 (JIP-1) (Davis et al., U.S. patent no 6,043,083). Using the full name of the gene at least once in the claims would alleviate this problem.

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Claims 1-3, 6-7, 11-12, 17, and 21 are free of the prior art of record given that the prior art does not teach or suggest a seed-preferred promoter sequence of SEQ ID NO:1 or similar sequence.

Claims 6 and 7 are objected to for reading on non-elected inventions, but would be allowable if the additional SEQ ID NO's were deleted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 305-3015.

Stuart Baum Ph.D.

January 14, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600

